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10/010,678	12/07/2001	Glenn J. Gormley	19109DE	1340

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1614

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 12

Application Number: 10/010,678
Filing Date: December 07, 2001
Appellant(s): GORMLEY ET AL.

MAILED
SEP 10 2003
GROUP 2000

Catherine D. Fitch
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 26, 2003.

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 16, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest, Merck & Co., Inc., is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct in noting that the amendment filed April 25, 2003 was not entered because it raise new issues that would require further consideration. In addition to that the amendment have not been entered because they are not deemed to place application under the allowable condition. Since the amendment is filed after the prosecution closed, the amendment has not been entered and thus the reader is directed to Appendix I for the claims on appeal.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct. The first issue on appeal is rejection under 102 and second issue is rejection under 103 as mentioned in the brief.

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(7) Grouping of Claims

The appellant's statement regarding grouping of claims in the brief is correct.

Appellant stated that the claims of groups I-III are considered to be separately patentable and do not stand of fall together. Although the examiner agreed on the grouping of the claims into 3 separate groups, the examiner wonder why appellant's grouping of the claims is seemed to be contradictory to their own argument. Based on appellant's argument in the brief, appellant should have grouped the all the claims into 1 group instead of 3 separate groups because appellants argue that transdermal administration should have been linked to the use of transdermal skin patches only, see the brief, at page 7, lines 32-33 whereas the examiner traverse that by stating that transdermal administration(broader scope) is not same as transdermal administration using skin patchs(narrower scope).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix I to the brief is correct.

(9) Prior Art of Record

✓ EP0285382 A2	Rasmusson et al	0
✓ US5407944	Goldman	0

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

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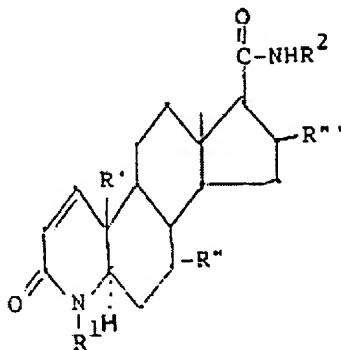
Claims 28-29 and 31-34 are rejected under 35 U.S.C. 102(b) and Claims 30 and 35-37 are rejected under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

1. Claims 28-29 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Rasmusson et al (EP 0285382 A2).

Rasmusson teaches a treatment of androgenic alopecia using topical 5 alpha reductase inhibitors(e.g.17-beta-N-monosubstituted-carbamoyl-4-aza-5alpha-androst-1-ene-3-ones) such as in the form of cream, lotion or ointment, see examples and claims. Rasmusson also teaches the limitations recited in claims 29 and 34 (i.e. a treatment of male pattern baldness) and the species required by claim 33 (i.e. 17 β -(N-tert-butylcarbamoyl)-4-aza-5 α -androst-1-ene-3-one) as a preferred species, see abstract; page 2, line 47; examples 6-12 and claims 1-4 and 6-8. It also teaches the patented compounds having the formula found in patented claim 1 as follows:

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(wherein:

R¹ is hydrogen, methyl or ethyl;

R² is a branched chain alkyl of from 3-12 carbon atoms;

R' is hydrogen or methyl;

R'' is hydrogen or β -methyl;R''' is hydrogen, α -methyl or β -methyl) for the manufacture of a medicament useful for treating androgenic alopecia.

The formulas I and II required by the instant claims 31 and 32 are encompassed by the patented formula shown above(supra). Even though the instant claims use the term "5alpha-reductase 2 inhibitor" whereas Rasmusson(EP'382) uses the term "5alpha-reductase inhibitor", they are considered to be the same or inherently same since they have same structure and utility. All the critical elements required by the instant claims are taught by the cited reference. Thus, all the claimed subject matter is rejected over the prior art of the record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. Claims 30 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmusson et al (EP 0285382 A2) in view of Goldman(US 5,407,944).

Rasmusson et al's teaching is mentioned in 102 rejection. For instance, the examples and claim 8 teach various alternative topical formulations including solution, cream, ointment, gel, shampoo or aerosol. Rasmusson teaches most elements required by the instant claims 30 and 35-37 except a topical application being formulated in the form of a transdermal skin patch.

However, it would be obvious to one of ordinary skill in the art to make a transdermal skin patch comprising a 5α -reductase 2 inhibitor to treat androgenic alopecia(e.g. male pattern baldness) when Rasmusson's reference is modified with Goldman because Goldman suggests that a pharmaceutical preparation could be made in the form of a topical transdermal skin patch comprising a composition containing 5α -reductase 2 inhibitor (e.g. finasteride®), see column 6, lines 10 and 20, especially line 28 and claims. For instance, Claims 17 and 19 contemplates a method for promoting hair growth using topical application of a vasodilator in combination with a 5α -reductase inhibitor. In addition to the techniques for formulating a transdermal patch from the topical formulations is generally well within the skilled level of the artisan having ordinary skill in the art, one would have had the reasonable expectation of success for treating androgenic alopecia by utilizing a skin patch formulation of 5α -reductase 2 inhibitor as an active component as suggested in Goldman. Thus, one would have been motivated to modify Rasmusson's teaching to include a transdermal skin patch to extend the applicability and acceptance by the patient who prefers a patch

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application to fit their needs, wherein the increased compliance would enhance the therapeutic efficacy and achieve cost-effective treatment via short duration of therapy and because this is seen as an alternative means to deliver medications. It is noted that finasteride® is 17 β -(N-tert-butylcarbamoyl)-4-aza-5 α -androst-1-ene-3-one.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

(11) *Response to Argument*

The 35 U.S.C. 102 (b) Novelty Rejection of Claims 28-29 and 31-34 is Improper

1. In respect to appellants argument that the examiner improperly interpreted the critical element in the claims, where the examiner read "transdermally administering" claim limitation as being encompassed within topical composition(e.g. cream, lotion or ointment) recited by the Rasmusson reference, the argument, however, is not persuasive because of the reasons as following:

The term "transdermal" is conventional term and the broadest interpretation is given where the transdermal(through-the skin) using any external skin formulation applied directly into the affected skin area. The examiner's interpretation of the term is based on the dictionary available to the ordinary artisan. The term "transdermal" includes any application that is applied through the unbroken skin(refers to medications applied directly to the skin(creams, ointments, patch, etc), see dictionary, World net 1.7

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or Webster(copies are enclosed in PTO-892). Although, appellants prefer the claim language to be understood as "use of transdermal skin patch", the claims are not drafted as clear as it should be, and the claims would not be interpreted narrower than what it is known to the ordinary skilled artisan. For the above reasons, it is believed that the 102 rejections(anticipated by Rasmusson) should be sustained. It is noted that appellants statement where appellants claim that the groups I-II are considered to be separately patentable and do not stand or fall together(see brief, at page 3, 4th paragraph), is self-evidentiary admission that appellants believe that transdermal administration is broader than skin-patch administration and different from skin patch administration.

The 103(a) Obviousness Rejection of Claims 36-37 is Improper

---(should be claims 30 and 36-37(due to the limitation, "skin patch"), thus it is corrected to claims 30 and 36-37 for the purpose of this Appeal).

2. In response to the appellants second argument that the examiner failed to establish a prima facie case of obviousness because Goldman's reference teaching away from appellant's invention in addition to the lack of anticipatory teaching by Rasmusson's reference. The examiner's response in respect to the Rasmusson's teaching is mentioned immediately above. Thus, the examiner's response is now specifically directed to the Goldman's teaching and the motivation to combine how it remedy the deficiency of the Rasmusson's teaching.

Goldman(US'889, hereafter) teaches a composition and a method for promoting hair growth and treating baldness(e.g. male pattern baldness) wherein the composition employ a vasodilator in combination with 5-alpha-reductase inhibitor and estradiol, see abstract. Appellants allege that Goldman's teaching should be limited to the tablet formulation of 5 alpha reductase inhibitor, see brief at page 11, 2nd-3rd paragraphs.

Appellants state, "Goldman recites certain commercially-available formulations.....(9) Finasteride as a tablet (col. 5, lines 43-62)

.....Goldman teaches away from and discourages Appellants to try a trans dermal skin patch containing 5 alpha-reductase type 2 inhibitors, because Goldman exemplifies vasodilators and estradiols as transdermal patches but discloses 5 alpha reductase inhibitors in the form of a tablet only"

The appellant's interpretation is narrower than what the patented invention is teaching wherein the patented invention teaches various formulations(e.g. tabler, cream, ointment, skin patches, etc) and routes of administration for optimal therapeutic efficacy. For instance, US'889 (Goldman) teaches that the patented invention is directed **a mixture of vasodilator and 5-alpha-reductase inhibitor in a topical unit dosage form**(emphasis added), see column 2, lines 14-16. US'889 also teaches that a pharmaceutical preparation(patented invention) **in unit dosage form** for administration to promote hair growth wherein the preparation comprises **about 0.5 to about 15mg finasteride and** such unit dosage preparations may likewise **to be prepared in unit dosage form in a topical form**, see column 6, lines 20-32. Goldman also teaches that **topical administration includes the administration using transdermal patches ,**

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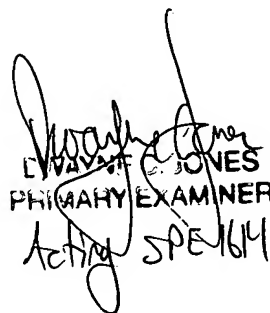
see column 6, lines 8-10. Thus, the administration using transdermal skin patch that comprising 5-alpha-reductase-inhibitor such as finasteride®(17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, species recited in claims 33, 35 and 37) should be encompassed by the scope of the patented invention. It is improper to separate the part of the disclosure to understand the whole invention whereas it is rather proper to read entire text as a whole to understand the invention. As stated in the patent(see column 5, lines 57-65), the teaching of US'889 should include that minor variations including dosage regimen, formulation, duration and other factors should be interdependent and individually titrated in order to achieve an optimal clinical response.

For the above reasons, it is believed that the 103 rejections(unpatentable over Rasmusson in view of Goldman) should be sustained.

Respectfully submitted,




Vickie Kim
Patnet examiner
Art unit 1614
August 28, 2003



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